

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



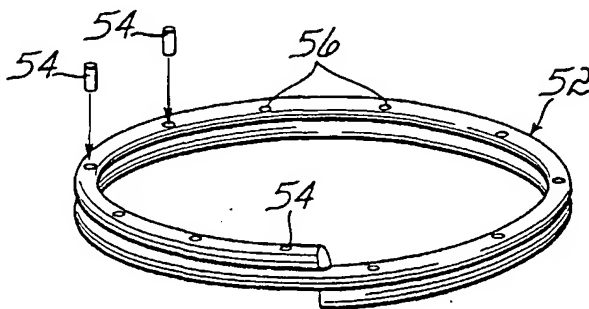
(43) International Publication Date
17 January 2002 (17.01.2002)

PCT

(10) International Publication Number
WO 02/03892 A1

- (51) International Patent Classification⁷: **A61F 2/24**
- (21) International Application Number: PCT/US01/17534
- (22) International Filing Date: 31 May 2001 (31.05.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/610,784 6 July 2000 (06.07.2000) US
- (71) Applicant and
(72) Inventor: **SPENCE, Paul, A.** [CA/US]; 5818 Orion Road,
Louisville, KY 40222 (US).
- (72) Inventors: **ORTIZ, Mark**; 1145 Glen Echo Lane, Mil-
ford, OH 45150 (US). **WHEDON, Randy**; 7855 Palace
Drive, Cincinnati, OH 45249 (US).
- (74) Agents: **ROONEY, Kevin, G.**; Wood, Herron & Evans.
L.L.P., 2700 Carew Tower, Cincinnati, OH 45202 et al.
(US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK,
SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments
- For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ANNULOPLASTY DEVICES



member (42) into position on one side of the valve annulus (20) and positioning at least a second ring of the coil-shaped member (42) on an opposite side of the valve annulus (20).

(57) Abstract: Devices for repairing and replacing a heart valve (18) in various embodiments, the devices (42) include at least first and second support rings connected together in a coiled configuration to abut opposite sides of a valve annulus (20). A replacement valve (260) may be secured to the coil-shaped device (262). Various alternative fastening systems include suture fastening systems, mechanical fastening systems, shape memory alloy fastening systems and other fastening systems relying only on the resilience between adjacent coils. A method generally includes inserting a first end of the coil-shaped member (42) through a valve annulus (20), rotating a first ring of the coil-shaped

ANNULOPLASTY DEVICES

Field of the Invention

The present invention generally relates to heart valve repair and replacement techniques and annuloplasty devices. More specifically, the invention relates to the repair and/or replacement of heart valves having various malformations and dysfunctions.

Background of the Invention

Diseased mitral and tricuspid valves frequently need replacement or repair. The mitral and tricuspid valve leaflets or supporting chordae may degenerate and weaken or the annulus may dilate leading to valve leak (insufficiency). The leaflets and chords may become calcified and thickened rendering them stenotic (obstructing forward flow). Finally, the valve relies on insertion of the chordae inside the ventricle. If the ventricle changes in shape, the valve support may become non-functional and the valve may leak.

Mitral and tricuspid valve replacement and repair are traditionally performed with a suture technique. During valve replacement, sutures are spaced around the annulus (the point where the valve leaflet attaches to the heart) and then the sutures are attached to a prosthetic

valve. The valve is lowered into position and when the sutures are tied, the valve is fastened to the annulus. The surgeon may remove all or part of the valve leaflets before inserting the prosthetic valve. In valve repair, a diseased valve is left in situ and surgical procedures are performed to restore its function. Frequently an annuloplasty ring is used to reduce the size of the annulus. The ring serves to reduce the diameter of the annulus and allow the leaflets to oppose each other normally. Sutures are used to attach a prosthetic ring to the annulus and to assist in plicating the annulus.

In general, annuloplasty rings and replacement valves must be sutured to the valve annulus and this is time consuming and tedious. If the ring is severely malpositioned, then the stitches must be removed and the ring repositioned relative to the valve annulus during restitching. In other cases, a less than optimum annuloplasty may be tolerated by the surgeon rather than lengthening the time of surgery to restitch the ring.

During heart surgery, a premium is placed on reducing the amount of time used to replace and repair valves as the heart is frequently arrested and without perfusion. It would be very useful to have a method to efficiently attach a prosthesis into the mitral or tricuspid valve position. Furthermore such a method may have its greatest advantage in remotely attaching a valve repair or replacement device so that surgery could be avoided altogether.

Annuloplasty devices and methods and heart valve repair and replacement devices and techniques are therefore necessary to provide a more reliable and more easily accomplished valve repair and replacement.

Summary of the Invention

The present invention generally provides a device for repairing a heart valve having an annulus and a plurality of leaflets for allowing and preventing blood flow through a patient's heart. The device comprises a first support ring and a second support ring connected to the first support ring to form a coiled configuration. The first support ring is configured to abut one side of the valve annulus and the second support ring is configured to abut an opposite side of the valve annulus to thereby trap valve tissue, that is, annulus tissue and/or leaflet tissue, therebetween.

5 This device may be used in those situations, for example, that have conventionally utilized annuloplasty rings, but the device of this invention may be applied in a much easier manner. The device may also be used to carry a replacement heart valve. The invention contemplates various embodiments of the device, including embodiments for catheter-based

10 surgery and embodiments for open heart surgery.

In the various embodiments, the first and second support rings may have an inner core covered by an outer layer, such as a fabric layer, with the inner core being formed from a more rigid material than the outer layer. The first and second support rings may have generally triangular-shaped cross sections with flat sides opposing one another and trapping valve tissue therebetween. A plurality of fasteners may be used between the first and second support rings and, for example, these may comprise sharp projections. An actuating member may be used to actuate the fasteners to an extended position through the valve tissue. Other forms of

20

fasteners are possible as well, including those comprising projections and complimentary receiving members on the first and second support rings. Shape memory alloys may be used to facilitate connection, such as by moving the first and second support rings together or moving fastening
5 elements thereof into engagement.

At least the opposed surfaces of the first and second support rings may be roughened, such as by the use of fabric, coatings, knurling or the like to facilitate better engagement and retention of the support rings on the valve tissue. A removable sleeve may be carried by the first and second
10 support rings for initially reducing friction between the respective rings and the valve tissue during initial engagement therewith, such as during rotation of the device on either side of the annulus. The sleeve may then be removed to expose the higher friction surfaces of the device to the valve tissue for better retention.

15 Preferably, the first and second support rings are formed integrally from a coiled rod, such as a metallic rod, with one end of the rod formed as a leading end and one end formed as a trailing end. These ends may be bent in opposite directions so that the leading end may be directed through the valve tissue and the trailing end may be grasped by an
20 appropriate surgical implement. A carrier may be used to rotate the device into position on opposite sides of the valve annulus and then may be removed leaving the first and second support rings in place to trap the valve tissue therebetween. As another alternative, the carrier may be coil-shaped and the repair device may be rotated into place on only one side of the

valve annulus similar to conventional rings. The carrier may then be rotated for removal while leaving the repair device in place. The first and second support rings may be adjustable in diameter to allow adjustment of the valve annulus.

5 When replacing a heart valve, a device of this invention again preferably comprises first and second support rings formed in a coiled configuration with a replacement valve coupled to at least one of the support rings. The replacement valve may be coupled in a releasable manner using any suitable fastening structure. For example, the
10 replacement valve and one of the support rings may include mating engagement elements or the replacement valve may be directly threaded into one of the support rings. The replacement valve and one of the support rings may alternatively include respective cuffs adapted to receive sutures to fasten the replacement valve to the support ring. Optionally, one
15 of the support rings may include a cuff with a movable fastening element which is engageable with the replacement valve. The fastening element may be formed from a shape memory alloy to facilitate its movement between an engaged and a disengaged position relative to the replacement valve.

20 The invention further contemplates various methods of repairing a heart valve including methods for fully replacing the heart valve. Generally, the method includes inserting a first end of a coil-shaped support through the tissue of a heart valve. A first ring of the coil-shaped support is then rotated in position on a first side of the annulus and a second ring of

the coil-shaped support is positioned on an opposite side of the annulus.

The first and second rings may then be fastened together to trap the annulus tissue therebetween, or the inherent resilience between the first and second rings may trap tissue without using separate fasteners. The

5 coil-shaped support may be carried in its coiled form during the rotation step, or the coil-shaped support may be extended from a catheter positioned adjacent the annulus. Many other variations of these methods and additional methods will be apparent to those of ordinary skill upon review of this disclosure.

10 Various additional objectives, advantages and features of the invention will become more readily apparent to those of ordinary skill in the art upon review of the detailed description of the illustrative embodiments.

Brief Description of the Drawings

Figure 1 schematically illustrates a patient with a heart shown
15 in cross section and a device of the present invention schematically illustrated as supporting the mitral valve.

Figure 1A is a cross sectional view of the left ventricle showing the mitral valve and a catheter-based device of the invention in perspective.

20 Figure 2A is a partially sectioned perspective view of the mitral valve and the catheter-based device during the insertion procedure.

Figure 2B is a view similar to Figure 2A showing the device fully inserted beneath the mitral valve.

Figure 2C is a view similar to Figure 2B, but illustrating the device fully attached to the mitral valve.

Figure 3 is a transverse cross sectional view of the device shown in Figure 2C.

5 Figure 4 is a cross sectional view of another embodiment of the repair device.

Figure 5A is a cross sectional view, partially fragmented, to show one version of a fastening system for devices of the present invention.

10 Figure 5B is a cross sectional view similar to Figure 5, but illustrating engagement of the fasteners with the valve tissue.

Figure 6 is a cross sectional view similar to Figure 5B, but illustrating another alternative fastening system.

15 Figure 6A is a partially fragmented, cross sectional view of the catheter repair device.

Figure 6B is a partially fragmented, enlarged cross sectional view illustrating the device of Figure 6A inserting the heart valve repair device.

20 Figure 7 is a perspective view of another alternative heart valve repair device.

Figure 8 is a perspective view of another alternative valve repair device in a deactivated state.

Figure 9 is a perspective view of the device shown in Figure 8, but illustrating the activated state.

Figure 10 is a partially cross sectioned perspective view illustrating another embodiment of the heart valve repair device.

Figure 11 is an enlarged partial cross sectional view illustrating the device of Figure 10.

5 Figure 12 is a perspective view of another alternative heart valve repair device.

Figure 13 is an enlarged view of encircled portion 12A of Figure 12 showing the coils separated.

Figure 14 is a perspective view illustrating the application of a
10 *heart valve repair device of the present invention to a mitral valve.*

Figure 15 is a perspective view similar to Figure 14, but illustrating insertion of the leading end of the device into the valve annulus.

Figure 16 is a perspective view similar to Figure 15, but illustrating the repair device fully applied to the valve.

15 Figure 17 is a cross sectional view taken along line 17-17 of Figure 14.

Figure 18A is a cross sectional view taken along line 18-18 of Figure 16, illustrating one fastening system of the invention is a deactivated state.

20 Figure 18B is a cross sectional view similar to Figure 18A, but illustrating the activated state of the fastening system.

Figure 19 is an elevational view of a heart valve repair device of the present invention applied to a tricuspid valve.

Figure 20 is a perspective view illustrating another repair device of the present invention being applied to a mitral valve.

Figure 21 is a view similar to Figure 20, but illustrating two of the devices applied to the mitral valve.

5 Figure 22 is a partially fragmented perspective view of another alternative heart valve repair device of the invention.

Figure 23 is a perspective view of another alternative heart valve repair device.

10 Figure 24 is a perspective view of another alternative heart valve repair device.

Figure 25 is a fragmented, cross sectional view showing another alternative fastening system for repair devices of the invention.

Figure 26 is an exploded perspective view of one heart valve replacement device of the present invention.

15 Figure 27 is a transverse cross sectional view of another alternative heart valve replacement device.

Figure 28 is a fragmented, cross sectional view of another alternative heart valve repair device.

20 Figure 29 is a plan view of another alternative heart valve repair device.

Figure 29A is a transverse cross sectional view of the repair device shown in Figure 29.

Figure 29B is a transverse cross sectional view similar to Figure 29A, but illustrating another alternative configuration.

Figure 30 is a cross sectional view of another alternative fastening structure for devices of the present invention.

Figure 31 is a perspective view, illustrating another alternative heart valve repair device being applied to a mitral valve.

5 Figure 32 is a side view of the device shown in Figure 31 shown being applied around the mitral valve annulus.

Figure 33 is a transverse cross sectional view of an alternative construction of the coil-shaped repair device of this invention.

10 Figure 34A is a sectioned, perspective view of another alternative heart valve repair device.

Figure 34B is a cross sectional view of the device shown in Figure 34A and illustrating connection thereof to valve tissue.

Figure 35A is a cross sectional view similar to Figure 34B, but illustrating an alternative fastening system.

15 Figure 35B is a cross sectional view similar to Figure 35A, but illustrating the repair device fastened to the valve tissue.

Figure 36 is a side elevational view showing another alternative heart valve replacement device of the invention.

20 Figure 37 is a side elevational view similar to Figure 36, but illustrating full connection between the replacement valve and coil support member.

Figure 38 is a top view of a mitral valve and an alternative heart valve repair device applied thereto.

Figures 39A-D are schematic views illustrating the process steps for replacing a valve in accordance with another embodiment of the invention.

Figure 40 is a cross sectional view illustrating another
5 alternative heart valve repair device.

Figures 41A and 41B are cross sectioned perspective views illustrating the steps in applying another alternative repair device to a heart valve.

Figure 42 is a cross sectional view showing another alternative
10 heart valve repair device applied to a heart valve annulus.

Figure 43 is a perspective view showing another alternative heart valve replacement device in accordance with the invention.

Detailed Description of the Preferred Embodiments

Figure 1 illustrates a patient 10 having a heart 12 shown in
15 cross section including a left ventricle 14 and a right ventricle 16. The concepts of the present invention are suitable to be applied, for example, to a mitral valve 18 which supplies blood into left ventricle 14. Mitral valve 18, as better shown in Figure 1A, includes an annulus 20 and a pair of leaflets 22, 24 which selectively allow and prevent blood flow into left
20 ventricle 14. It will be appreciated that the term annulus tissue is used extensively throughout this disclosure in reference to the drawings, however, the inventive principles are equally applicable when referring to other valve tissue such as leaflet tissue or other attached vessel tissue.

Leaflets 22, 24 are supported for coaptation by chordae tendinae or chords 26, 28 extending upwardly from respective papillary muscles 30, 32. Blood enters left ventricle 14 through mitral valve 18 and is expelled during subsequent contraction of heart 12 through aortic valve 34. It will be appreciated that the present invention is applicable to heart valves other than the mitral valve in various of its aspects to be described below.

One preferred device of the present invention is shown in Figures 2A-2C and Figure 3 and is applied through the use of a catheter 40 inserted into the appropriate region of heart 12, such as above mitral valve 18, by conventional techniques such as through a femoral artery. A flexible elongate support member 42 is contained in a movable manner within catheter 40 and, when extended therefrom as shown in Figures 2A-2C, assumes a spiral or keyring-type configuration. Any suitable medical grade material(s), such as medical grade metals or plastics, may be used to form elongate support member 42. One form is shown in cross section in Figure 3 and comprises an inner core 44 surrounded by an outer layer 46. Inner core 44 may be formed from a more rigid material, such as metal or plastic, while outer layer 46 may be formed from a softer layer, such as fabric. Another alternative flexible elongate support member 42' is shown in Figure 4. This embodiment has a traditional cross sectional shape associated with a keyring. In this embodiment flat, opposed surfaces 42a' trap valve annulus tissue 20 therebetween.

As shown in Figure 2A, catheter 40 is inserted until an open end 40a thereof is positioned adjacent annulus 20. Support member 42 is

then extended through annulus 20 and pushed outward from catheter 40 to assume its pre-stressed coiled shape beneath mitral valve 18 generally adjacent annulus 20 as shown in Figure 2B. As further shown in Figure 2B, catheter 40 is then withdrawn with respect to support member 42 to
5 release the remaining portion of support member 42 into the pre-stressed coiled shape above mitral valve 18 such that annulus 20 is trapped between adjacent coils of support member 42.

Figures 5A and 5B illustrate an embodiment of support member 42 in which internal core 44 includes barbs 44a which are movable
10 between extended and retracted positions. In the retracted position shown in Figure 5A, barbs 44a do not engage valve annulus tissue 20. When internal core 44 is pulled in the direction of the arrow in Figure 5A, barbs 44a extend through outer layer 46 and into valve annulus 20. This retains flexible elongate support member 42 in place on valve annulus 20. Figure 6
15 illustrates another embodiment of a flexible elongate support member 42''. In this embodiment, internal core 44'' includes barbs 44a'' extendable from opposite directions into valve annulus 20 upon pulling the internal core 44'' in the direction shown by the arrows to facilitate additional securement.

Figures 6A and 6B illustrate cross sections of the catheter 40
20 and inner core 44 and one schematically illustrated actuation device 60. Specifically, a pair of jaws 62, 64 may be pivotally secured together and actuated between open and closed positions using cables 66, 68 to grip one end 44b of the inner core 44. The actuation device 60 may then be

pulled or pushed by the surgeon in the appropriate direction to extend or retract the barbs 44 (Figure 5A).

Figure 7 illustrates another embodiment of a flexible elongate support member 52 in the shape of a coil or, in other words, generally the shape of a keyring. In this embodiment, separate retaining members 54 may be inserted through respective holes 56 in adjacent coils of support member 52 to retain annulus tissue (not shown) therebetween. Retaining members 54 may be threaded or unthreaded pins and may be integrated directly into support member 52 for actuation between locking and unlocking positions relative to the valve annulus.

Figures 8 and 9 illustrate another embodiment of a coiled support member 70 in which the support member includes interlocking portions 70a, 70b. As one example, the coiled support member 70 may be inserted in a manner similar to the method described in connection with Figures 2A-2C and once inserted on opposite sides of the valve annulus, the coiled support member 70 may be activated to a locked position as shown in Figure 9. For example, the coiled support member 70 may be formed from a shape memory alloy and may be activated between the unlocked position shown in Figure 8 and the locked position shown in Figure 9 through the application of suitable electric current.

Figures 10 and 11 illustrate another alternative coil-shaped valve support member 80 which may again comprise an inner core (not shown) surrounded by an outer layer 82 of flexible fabric. In such constructions, the friction created by the outer layer 82 may make insertion

of the coil member 80 difficult, especially in cases in which coil member 80 is simply manually turned into position as described below. Therefore, in this embodiment a sleeve 84 is provided on the outside of the coil member 80. The sleeve 84 is formed of a low friction material such as PTFE or Teflon®, or another similar material. This low friction material will make insertion of the coil member 80 easier by simply rotating the coil member 80 into place through a suitable slit or hole formed through the valve annulus 20. Once the coil member 80 is inserted as shown in Figure 10, the sleeve 84 may be pulled off of the coil member 80 and discarded. Alternatively, sleeve 84 may be a coating that is absorbable or that may be rinsed off after fulfilling its function of easing insertion.

Figures 12 and 13 illustrate another alternative valve support member 90 in the shape of a coil or keyring. This embodiment also illustrates retaining members 92 in the form of small threaded fasteners as generally described in connection with Figure 7. As shown best in Figure 13, a coating of softer cushioning material 94, 96 may be applied to surfaces of the coil member 90 which oppose one another and contact opposite sides of the valve annulus (not shown). In addition to cushioning the contact areas with the annulus tissue, these coatings 94, 96 may provide additional friction to retain the coil member 90 in place. Again, a low friction sleeve (not shown) may be used as described in connection with Figures 10 and 11 to ease insertion of coil member 90 above and below the valve.

Figures 14-16 illustrate another alternative for installing a coil member 100 constructed generally in accordance with the invention. A temporary holder 102 is coupled between the coils and includes a handle portion 104 for allowing rotation of coil member 100 about a central axis defined generally along the length of handle portion 104. A small incision or hole 106 is made in annulus 20 as shown in Figure 14 and a starting end 100a of the coil member 100 is inserted through the incision 106 as shown in Figure 15. Handle portion 104 is rotated until at least approximately one coil is beneath the valve 18 and one coil remains above the valve 18 to trap the annulus tissue 20 therebetween as generally described above and as shown in Figure 16.

Figures 17 and 18A-18B illustrate another alternative locking structure usable with the embodiment shown in Figures 14-16. In this regard, a core 110 may be pulled and used to actuate a cam mechanism 112 to drive a series of barbs or other fastening members 114 connected to a carrier 116 through the annulus tissue 20 and, optionally, into a soft coating 118, such as silicone, disposed on the opposite coil. The core 110 may then be cut and knotted to prevent movement thereof in the opposite direction such that the cam mechanism 112 retains the barbs or other fastening members 114 in the position shown in Figure 18B.

Figure 19 illustrates a valve support member 120 specifically configured for a tricuspid valve 122 and which may be otherwise formed as a coil as generally discussed herein, and by including fasteners or locking elements 124.

Figures 20 and 21 illustrate generally C-shaped support members 130 which include first and second connected legs 130a, 130b for locking on opposite sides of a valve, such as a mitral valve 18, as shown in Figure 21. Each C-shaped valve support member 130 is inserted
5 through an incision 134 such that legs 130a, 130b trap annulus tissue 20 therebetween as shown in Figure 20. A core 136 is used to activate a locking mechanism (not shown), such as the mechanisms previously described.

Figure 22 illustrates another alternative locking mechanism
10 used on a generally C-shaped valve support member 140. In this embodiment, the two opposing legs 140a, 140b are moved relatively toward each other such that a plurality of locking elements or barbs 142 engage the valve tissue (not shown) therebetween. Handle or actuating portions 144, 146 may then be removed by the surgeon.

15 Figure 23 illustrates a removable fabric sleeve 150 usable with or without the internal, more rigid portion 152 of a coil valve support member.

Figures 24 and 25 illustrate another alternative locking mechanism usable with coil valve support members of the present
20 invention. In this regard, a core 160 of coil member 162 actuates a flexible barb member 164 through the annulus tissue 20 and into an anvil portion 168 in an opposed coil portion 170. This effectively locks the barb member 164 into a hook shape within anvil portion 168 as shown to provide a more effective locking action.

Figure 26 illustrates another alternative embodiment of the invention utilizing a coil-type support member 180 for anchoring a replacement heart valve 182 in place once the coil-type support member 180 is turned into place around the native valve annulus and fixed into place, such as previously described, the native mitral valve 18 or other valve is cut away and replacement valve 182 may be locked onto the coil-type support member 180. The replacement valve 182 may be conventional or of any desired design and, in accordance with the invention, may include various types of connecting members for making the connection between the valve 182 and the support member 180. In the embodiment shown in Figure 26, this connection is made by projections 186 on the valve 182 which register with grooves, recesses or other slots 190 of support member 180. The projections 186 are inserted into one portion 190a of each slot 190 and turned to the end 190b of the slot as shown. Figure 27 illustrates a similar replacement valve 192, such as a valve having movable flaps 194, 196. The outer, annular portion 198 of the valve 192 includes an outer surface 198a which maybe be essentially threaded into a coil support member 200 such that it is secured in place above the native valve 202 as shown.

Figure 28 illustrates another manner of securing a replacement heart valve 210 to a coil-type support member 212 constructed in accordance with the invention as previously described. In this embodiment, the replacement valve 210 includes a cuff 214, for example, formed from a fabric and the coil-type support member 212 also includes a fabric cuff

216. The surgeon stitches the replacement valve 210 into place by suturing between the two cuffs 214, 216 with, for example, known suturing methods allowing the suture to be pulled tight to engage the two cuffs 214, 216 together and thereby form a seal.

5 Figures 29 and 29A illustrate an alternative coil-type support member 217 formed from a flat piece of material, such as metal or plastic. Figure 29B also illustrates an alternative coil-type support member 218 formed generally from a flat piece of material, such as metal or plastic, and having one substantially planar coil 218a and an adjacent undulating coil
10 218b.

 Figure 30 illustrates another alternative coil-type support member 219 affixed to an annulus 20 of a mitral valve 18 and including yet another distinct cross-sectional configuration. In particular, an upper coil includes a recess 219a and a lower coil includes a projection 219b received
15 in recess 219a and trapping tissue 20 therein. This may be desirable for gathering up excess annulus tissue.

 Figures 31 and 32 illustrates another modification to a coil-type support member 220 adapted to be secured around the annulus 20 of a valve, such as a mitral valve 18. In this embodiment, each end of the
20 coil-type support member 220 is turned or bent in an opposite direction. One end 220a is a starting end and is tapered for easier insertion into a small slit or hole 222 formed by the surgeon in the valve annulus 20. Another end 220b is turned upwardly for engagement by a suitable tool

-20-

224 used by the surgeon to turn the support member 220 into place around the valve annulus 20 as generally described above.

Figure 33 illustrates a cross section of one coil 226 of a coil-type support member showing an alternative cross-sectional construction.

5 In this regard, the coil 226 may be formed from a core 228 comprising low friction material, such as a low friction polymer, to expose a lower surface 228a for engagement with the annulus tissue (not shown) while the coil 226 is turned into place as generally described above. An outer surface or exposed surface 228b may be covered with a suitable fabric 230 such as a
10 conventional fabric used on annuloplasty rings. This fabric may be connected to the core 228 using suitable pins or staples 232 or by other fixation methods.

Figures 34A and 34B illustrate another alternative embodiment showing a coil-type support member 240 in cross section comprised of an
15 outer hollow carrier 242, which may be formed from a metal or generally rigid plastic, for example, and which holds a core portion 244. The coil support member 240 may be turned into place above and below a valve annulus 20, as previously described. With the outer carrier 242 in place as shown in Figure 34A, the internal core portion 244, which also has the
20 configuration of a coil, is held apart against its own natural bias to remain together with closely adjacent coils. When the hollow carrier 242 is removed as shown in Figure 34B, the internal core portion 244 springs together to its initial position and a plurality of projections, spikes or barbs 248 are driven into the valve annulus tissue 20 as shown in Figure 34B.

-21-

These spikes 248 may penetrate completely through the tissue 20 or only partially as shown.

Another alternative is shown in Figures 35A and 35B. In this regard, the outer carrier 242 carries an internal fabric core 250 and, after
5 the carrier 242 and core 250 are turned into place around the valve annulus 20 as shown in the cross section of Figure 35A, a plurality of pins 252 are driven through holes 254 in the carrier 242 and also through the fabric core 250 disposed on opposite sides of the valve annulus 20, as well as the valve annulus itself as shown in Figure 35B. After pins 252 are inserted
10 around the entire circumference of the valve annulus 20, the carrier 242 is turned out of position and removed to leave the fixed core 250 in place above and below the valve annulus 20 as shown in Figure 35B.

Figure 36 illustrates the insertion of a replacement valve 260 onto a coil-type support member 262 fixed to a valve annulus 20. In this
15 embodiment, the replacement valve 260 includes a cuff 264 on its outer periphery which receives an upper coil 262a of the support member 262 when turned in place as shown in Figure 37. It will be appreciated that the male-female coupling of cuff 264 and coil 262a could be reversed, e.g., coil 262a could carry a cuff which receives a coil or ring on valve 260.

20 Figure 38 illustrates another coil-type support member 270 secured around a mitral valve 18 and including an internal drawstring 272 which may be pulled in the direction of arrows 274 to reduce the diameter of the support member 270 and correspondingly reduce the diameter of the

-22-

mitral valve 18 as shown by arrows 276. The drawstring 272 may be tied to secure the valve 18 at the desired diameter.

Figures 39A-39D illustrate another alternative coil-type support member 280. In this embodiment the coils 280a, 280b are at least substantially concentric such that the support member 280 may be turned through a hole 282 in a vessel 284 and the coils 280a, 280b engage and trap the vessel 284 between the adjacent coils 280a, 280b. In the embodiment shown, a carrier 290 is used to turn the support member 280 into place as shown in Figures 39A and 39B and a replacement valve 292 may then be secured within the inner coil 280a as schematically shown in Figures 39C and 39D using one of the fixation methods described above or another suitable fixation method.

Figure 40 illustrates an undulating coil-type support member 300 shown in cross section having adjacent coils 300a, 300b trapping tissue, such as annulus tissue 20, therebetween. The construction of the support member 300 would otherwise be similar to the constructions described above. The undulations provide a manner of further securing the support member 300 to the tissue 20. As an additional securement method, the coils may contain aligned holes 302 for receiving, for example, a suture 304 through portions of the coil 300 and tissue 20 or through the entire circumferential extent of coil 300 for additional securement.

Figures 41A and 41B illustrate another alternative embodiment in which a coil member 310, for example, formed from a metal or relatively rigid plastic is used as a carrier for a fabric support member 312. The

-23-

fabric support member 312 may also be coil-shaped and, therefore, ultimately reside on both sides of annulus 20 or, alternatively, be ring-shaped or otherwise shaped to only reside on one side of annulus 20 similar to conventional annuloplasty rings. In this regard, the fabric support

5 member 312 may be temporarily sutured to the coil carrier 310 and the combination is turned into place above and below the valve annulus tissue 20. A lower coil 310a includes an anvil or recess 314, for example, and, once the combination 310, 312 is turned into place as shown in Figure 41A, a series of staples 316 may be deposited through the fabric support

10 member 312 to secure the fabric support member 312 to the valve annulus 20 as shown in Figure 41B. When a requisite number of staples 316 has been applied around the valve annulus 20, the coil carrier 310 may be turned out and removed after removing the temporary sutures (not shown) leaving the fabric support member 312 in place around all or a portion of

15 valve annulus 20.

As illustrated in Figure 42, another alternative heart valve replacement device 330 comprises a replacement valve having a pair of flaps 332, 334 coupled with an annular support member 336. It will be appreciated that each of the replacement valves is illustrated herein

20 schematically and these valves may take many different forms as is generally known in the art. A coil-shaped member 340 constructed generally as described for the previous embodiments of coil-shaped repair devices is secured around valve annulus 20. In this embodiment, device 340 may comprise a coil having an inner core 342 and an outer layer or cuff 344.

-24-

Cuff 344 contains a fastening ring 346 which is secured beneath a lip 336a of annular support member 336. In Figure 42, fastening ring 346 is shown engaged on the right-hand side and in the process of moving radially inward into engagement on the left-hand side. This engagement, for example, may occur through the use of a shape memory alloy which may be activated, for example, through the suitable application of electric current into fastening member 346 to move fastening member 346 into the fully engaged position beneath lip 336a.

Figure 43 illustrates another alternative heart valve replacement system including a replacement valve 350 including an annular fabric cuff 352. Cuff 352 receives sutures 354 which extend further through a cuff 360 associated with a coil-shaped device 362, such as one of the devices described above. At one point, cuff 352 is secured to cuff 360 by a hinge structure 364, which may also be formed with sutures. By suturing cuff 352 to cuff 360 around the entire annulus and pulling suture 354 taught, a sealing engagement is formed between cuff 352 and cuff 360 thereby fastening replacement valve 350 to device 362. The existing leaflets of mitral valve 18 are removed by the surgeon prior to fastening replacement valve 350 to device 362.

While the present invention has been illustrated by a description of preferred embodiments and while these embodiments have been described in some detail, it is not the intention of the Applicants to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled

in the art. The various features and concepts of the invention may be used alone or in numerous combinations depending on the needs and preferences of the user. This has been a description of the present invention, along with the preferred methods of practicing the present invention as currently
5 known. However, the invention itself should only be defined by the appended claims, wherein we claim:

-26-

1. A device for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:
 - a first support ring, and
 - 5 a second support ring connected to said first support ring to form a coiled configuration, said first support ring configured to abut one side of the valve and said second support ring configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween.
- 10 2. The device of claim 1, wherein said first and second support rings each have an inner core covered by an outer layer, said inner core formed from a more rigid material than said outer layer.
3. The device of claim 1, wherein said first and second support rings have generally triangular-shaped cross sections.
- 15 4. The device of claim 1, further comprising:
 - a plurality of fasteners extending between said first and second support rings.
5. The device of claim 4, wherein said fasteners comprise sharp projections.

6. The device of claim 4, wherein said fasteners comprises projections extending from said first support ring and receiving members on said second support ring configured to engage with said projections.
7. The device of claim 1, further comprising an actuating member
5 coupled to at least one of said support rings and operating to actuate the fasteners to an extended position through the valve tissue.
8. The device of claim 1, wherein said first and second support rings are formed from a shape memory alloy.
9. The device of claim 1, further comprising a removable material
10 on at least one of said first and second support rings for reducing friction between the respective rings and the valve tissue during initial engagement therewith, said material being removable to increase the friction during securement of the device to the valve tissue.
10. The device of claim 1, wherein opposed surfaces of said first
15 and second support rings are roughened to facilitate engagement with the valve tissue.
11. The device of claim 10, further comprising a coating of cushioning material on each of said opposed surfaces.

12. The device of claim 1, wherein each of said support rings is formed from a fabric material.
13. The device of claim 1, wherein at least one of said support rings includes undulations.
- 5 14. The device of claim 1, wherein said support rings are formed from a flat plate material.
15. The device of claim 1, wherein said first and second support rings are formed integrally from a coiled rod with one end of said rod formed a leading end on said first support ring and another end of said rod forming a trailing end on said second support ring.
- 10 16. The device of claim 15, wherein said leading and trailing ends are bent in generally opposite directions.
17. The device of claim 1, wherein said first and second support rings have a multi-layered construction including an inner layer of a first material and an outer layer of a second material, said inner layer having a lower coefficient of friction than said outer layer, and said inner layer being exposed on opposed surfaces of said first and second support rings which are adapted to engage the valve tissue there between.
- 15

18. The device of claim 1, further comprising a removable carrier configured to carry said first and second support rings into position on opposite sides of the valve and then be removed leaving said first and second support rings on opposite sides of the valve.

5 19. The device of claim 1, wherein said first and second support rings are adjustable in diameter to allow adjustment of the valve annulus.

20. A device for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:

10 a valve support device configured for attachment to at least one side of the heart valve, and

a coil-shaped carrier removably coupled with said valve support device for allowing said valve support device to be turned into position on said at least one side and secured to a portion of the valve tissue to support
15 the heart valve.

21. A device for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:

a catheter having a lumen and an open end,
20 an elongate valve support member carried within said lumen and movable from said open end, said elongate valve support member

having an uncoiled configuration within said lumen and assuming a coiled configuration when extended from said open end.

22. The device of claim 21, wherein said elongate valve support member including an inner core covered by an outer layer, said inner core
5 formed from a more rigid material than said outer layer.

23. The device of claim 21, wherein said elongate valve support member has a generally triangular-shaped cross section.

24. The device of 21 further comprising:
an actuator carried within said lumen and operable to extend
10 said elongate valve support member from said open end.

25. The device of claim 24, wherein said actuator further comprises a gripping element operable to grip and allow releasing of one end of said elongate valve support member.

26. The device of claim 21, wherein said elongate valve support
15 member is formed from a shape memory alloy.

-31-

27. A device for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:

a first support member at least partially formed from a shape memory alloy operable to assume an activated shape and an inactivated shape, and

a second support member at least partially formed from said shape memory alloy and connected to said first support member, said first support member configured to abut one side of the valve and said second support member configured to abut an opposite side of the valve, whereby a portion of the valve tissue is trapped between said first and second support members upon said shape memory alloy assuming said activated shape.

28. The device of claim 27, wherein said first and second support members are ring shaped.

29. The device of claim 27 further comprising:

a plurality of fastening elements on at least one of said first and second support members for engaging the valve tissue when the shape memory alloy is in the activated shape.

30. The device of claim 29, wherein said first support member includes at least one projection and said second support member includes at least one fastening portion to receive said projection.

31. A device for repairing a heart valve comprised of valve tissue
5 including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:
a carrier, and
a coil-shaped member connected to said carrier in a removable
manner, said coil-shaped member having a first support ring configured to
10 abut one side of the valve and a second support ring configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween.

32. The device of claim 31 further comprising:
a plurality of fasteners extending between said first and
15 second support rings.

33. The device of claim 32, wherein said fasteners comprise sharp projections.

34. A replacement valve device for replacing a heart valve of a patient, the device comprising:

a first support ring, and

a second support ring connected to said first support ring to
5 form a coiled configuration, said first support ring configured to abut one side of an area of valve tissue and said second support ring configured to abut an opposite side of the area of the valve tissue to thereby trap the valve tissue therebetween, and

a replacement valve coupled to said second support ring and
10 including at least one valve element extending within said second support ring for allowing and preventing blood flow therethrough.

35. The device of claim 34, wherein said replacement valve is coupled to said second support ring in a removable manner.

36. The device of claim 35, wherein said replacement valve and
15 said second support ring include mating engagement elements to allow coupling in the relatable manner.

37. The device of claim 35, wherein said replacement valve is threadable into said second support ring.

38. The device of claim 34, wherein said first and second support
20 rings are contained in generally the same plane.

-34-

39. The device of claim 34, wherein said first and second support rings are contained in substantially different planes.

40. The device of claim 34, wherein said replacement valve and said second support ring include respective cuffs adapted to receive sutures
5 applied therebetween to fasten said replacement valve to said second support ring.

41. The device of claim 34, wherein said second support ring includes a cuff containing a movable fastening element which is engageable with said replacement valve to couple said replacement valve to said second
10 support ring.

42. The device of claim 41, wherein said fastening element is formed from a shape memory alloy.

43. A method of repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing
15 blood flow, the method comprising:

inserting a first end of a coil-shaped support through a portion of the valve tissue,

rotating at least a first ring of the coil-shaped support to position the first ring on a first side of the valve, and

positioning at least a second ring of the coil-shaped support on an opposite second side of the valve.

44. The method of claim 43, further comprising:
fastening the first and second rings together to trap the valve
5 tissue therebetween.
45. The method of claim 44, wherein the step of fastening the first and second rings together further comprises:
inserting fasteners through said first and second rings and
through the valve tissue disposed therebetween.
- 10 46. The method of claim 44, wherein the step of fastening the first and second rings together further comprises:
activating a plurality of sharp projections from said first ring
toward said second ring and through the valve tissue disposed
therebetween.
- 15 47. The method of claim 43, wherein the inserting and rotating steps each further comprise:
extending the coil shaped support from a catheter.

-36-

48. The method of claim 43, wherein said coil shaped support is coupled with a carrier during the inserting, rotating and positioning steps, and the method further comprises:

removing the carrier after the positioning step.

5 49. The method of claim 48, further comprising:

driving a plurality of fastening elements through the coil shaped support and valve tissue, and against the carrier prior to removing the carrier.

50. The method of claim 43, wherein said coil shaped support
10 includes a material having a lower coefficient of friction than said outer surface, and the method further comprising:

performing at least the inserting and rotating steps with the material disposed on at least a portion of the outer surface, and
removing the material after the rotating step.

15 51. The method of claim 50 further comprising:
removing the material after the positioning step.

52. The method of claim 43, further comprising:
adjusting the diameter of at least one of said first and second
rings to adjust the diameter of the annulus.

-37-

53. The method of claim 43, further comprising:
coupling a replacement valve to at least one of said first and
second rings.

54. A method of replacing a heart valve of a patient, the method
5 comprising:
inserting a first end of a coil-shaped support through an area of
valve tissue,
rotating at least a first ring of the coil-shaped support to
position the first ring on a first side of the valve tissue,
10 positioning at least a second ring of the coil-shaped support on
an opposite second side of the valve tissue, and
coupling a replacement valve to at least one of the first and
second rings.

55. The method of claim 54, wherein the valve tissue is an annulus
15 associated with a native heart valve.

56. The method of claim 54, wherein coupling the replacement
valve further comprises suturing a cuff on the replacement valve to a cuff
on one of the first and second rings.

57. The method of claim 54, wherein coupling the replacement valve further comprises rotating the replacement valve into sealing engagement with one of the first and second rings.

58. The method of claim 54, wherein coupling the replacement
5 valve further comprises rotating a cuff on the replacement valve over one of the first and second rings.

59. The method of claim 54, wherein coupling the replacement valve further comprises activating a fastening element formed from a shape memory alloy.

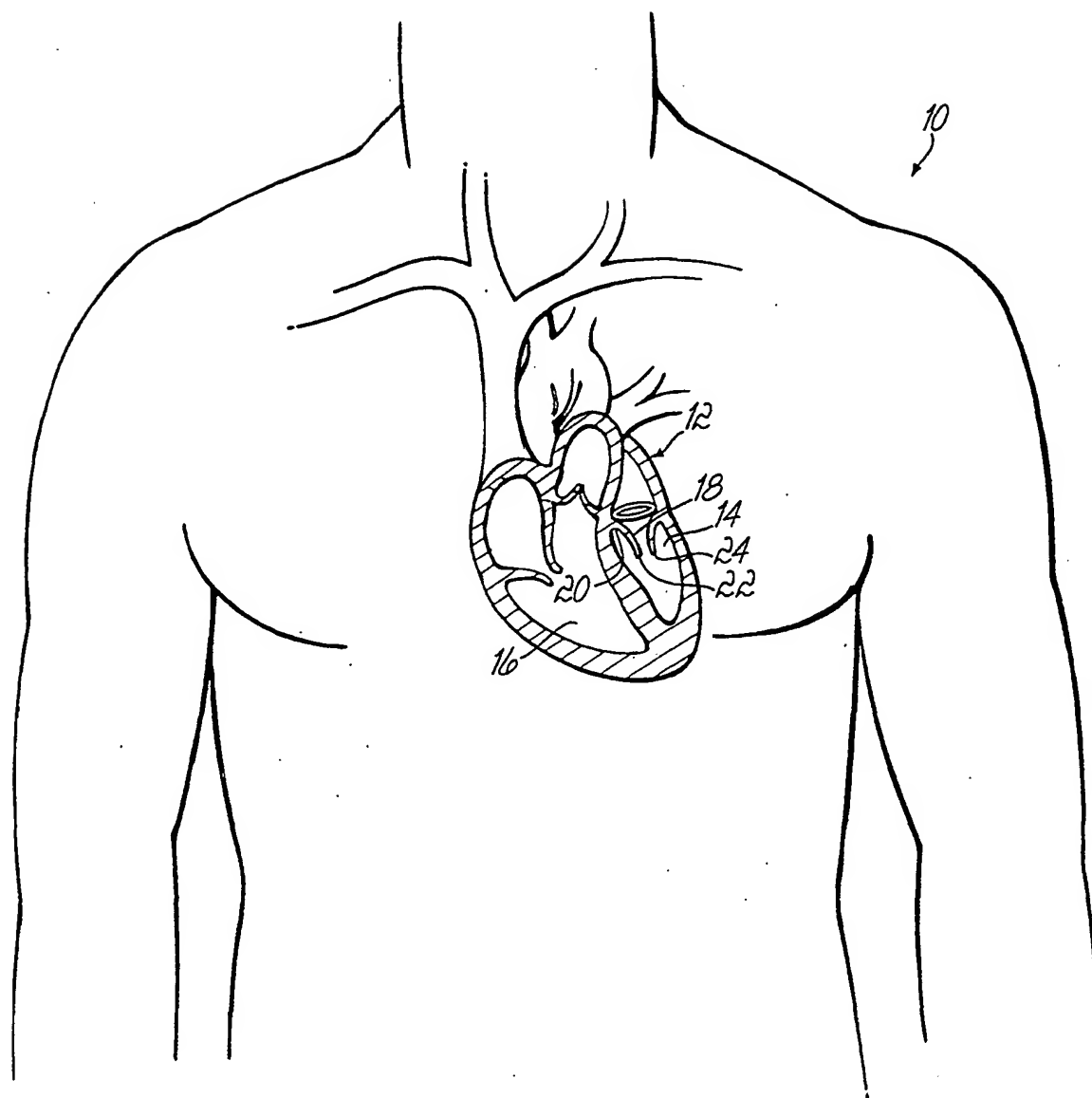


FIG. 1

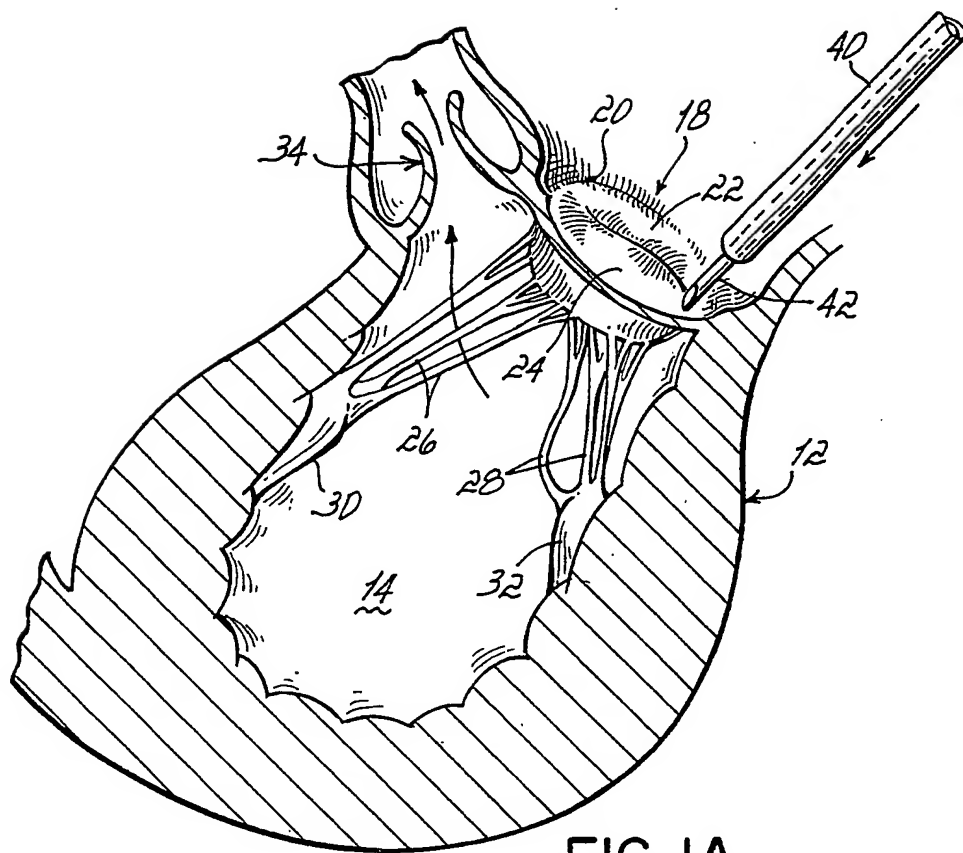


FIG. 1A

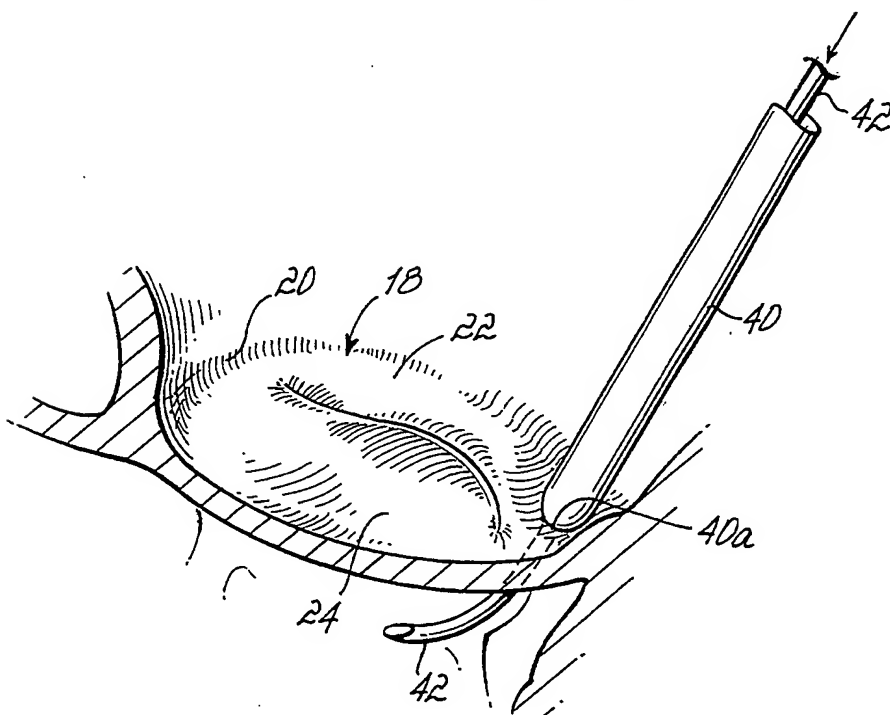


FIG. 2A

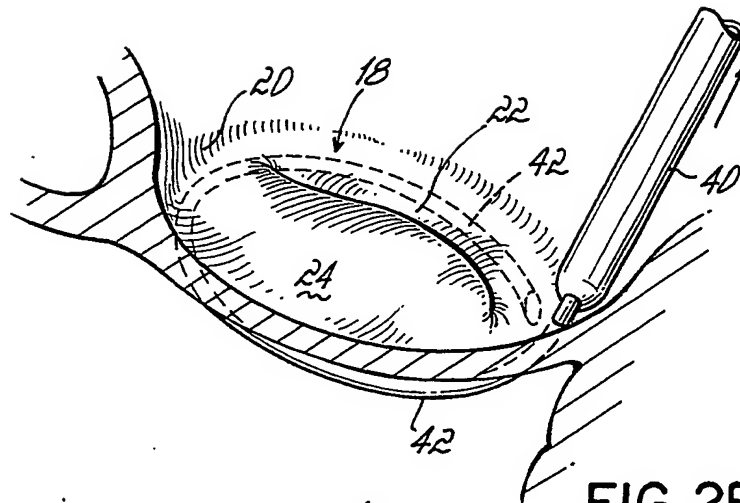


FIG. 2B

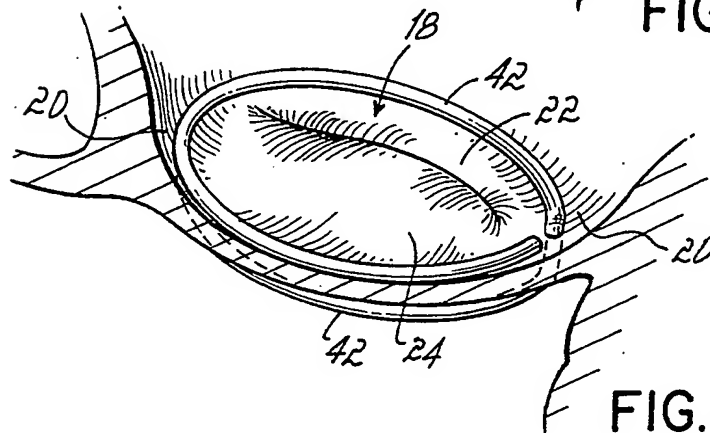


FIG. 2C

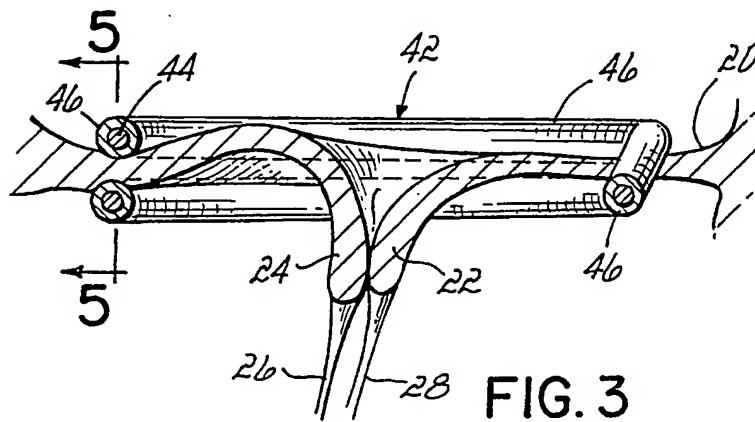


FIG. 3

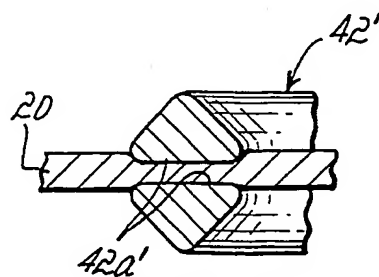
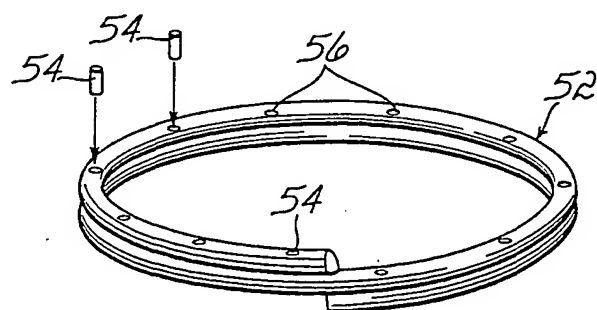
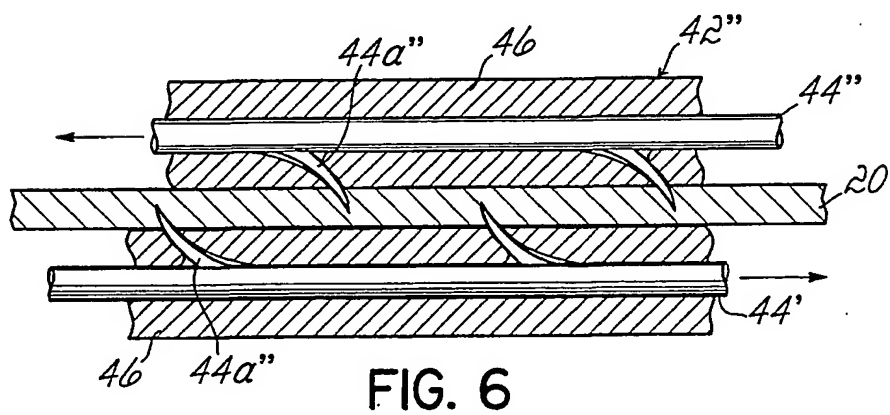
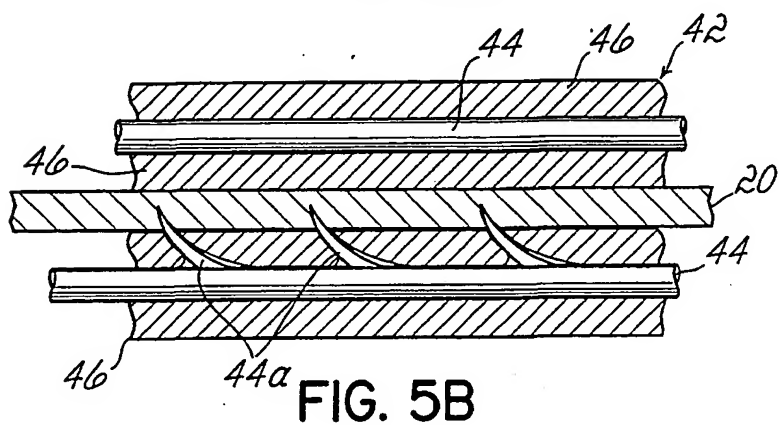
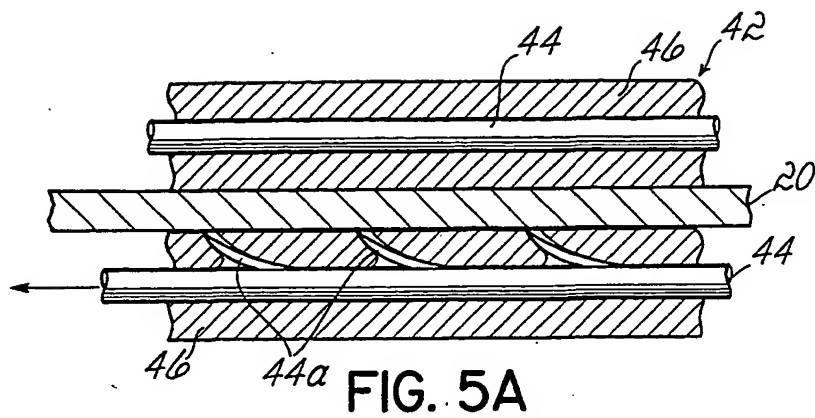


FIG. 4



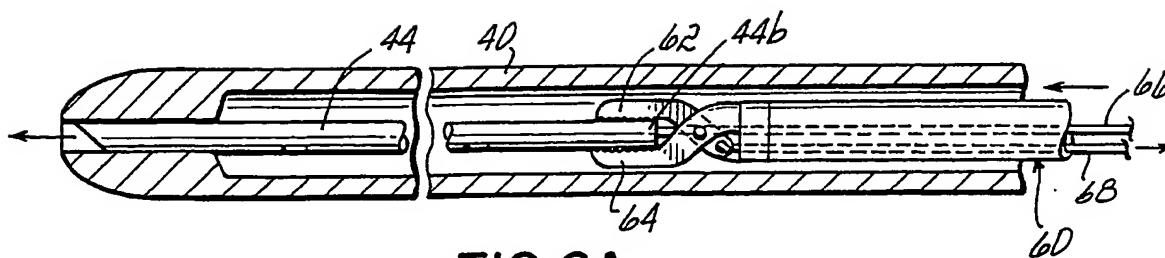


FIG. 6A

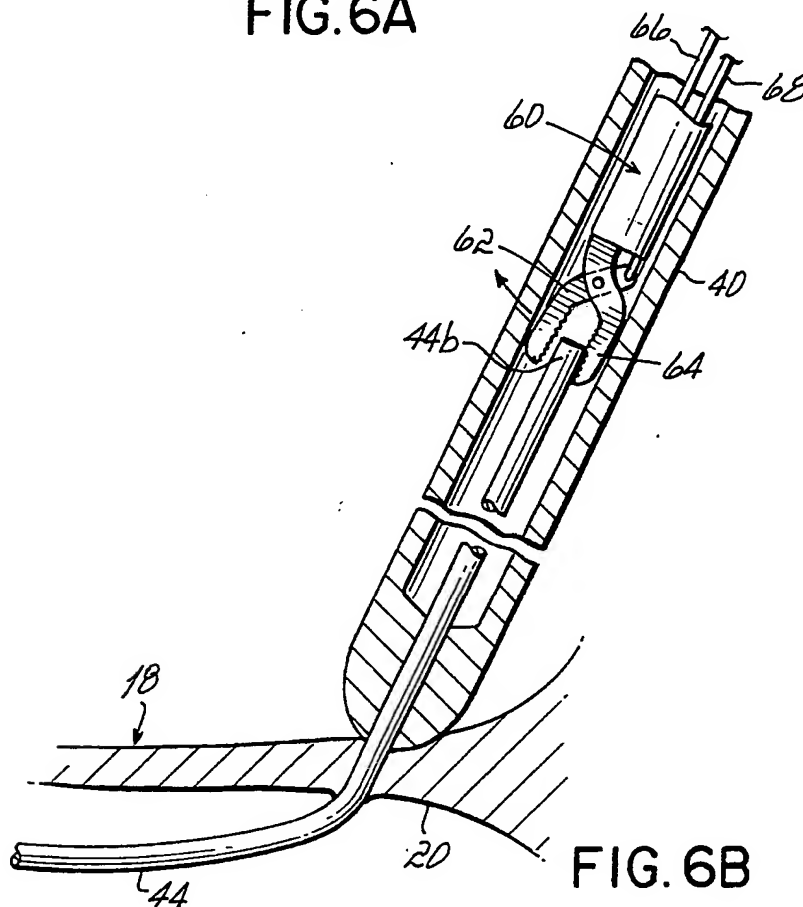


FIG. 6B

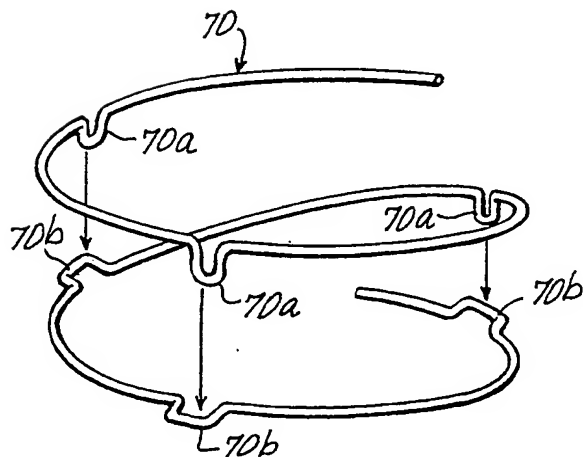


FIG. 8

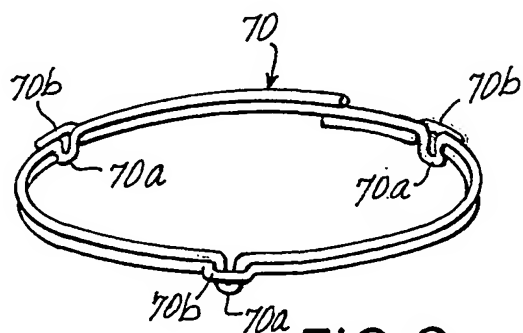


FIG. 9

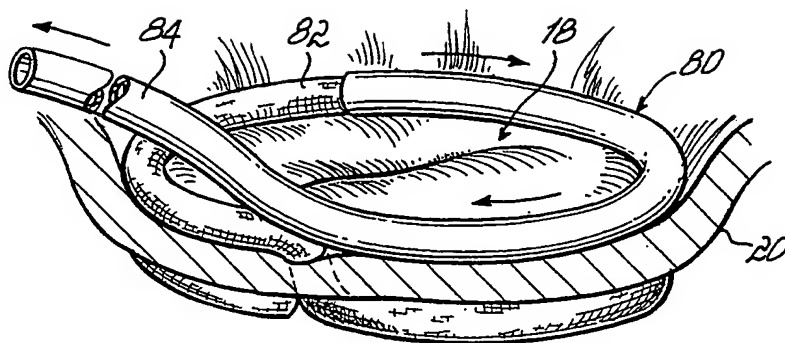


FIG. 10

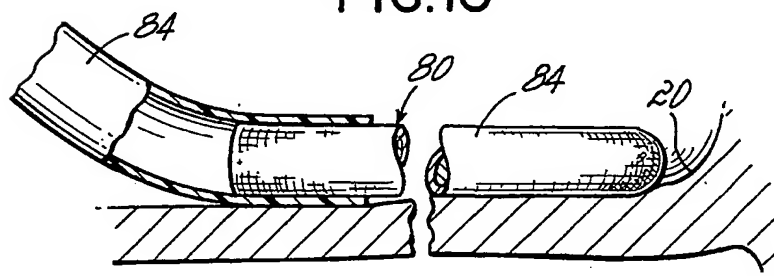


FIG. 11

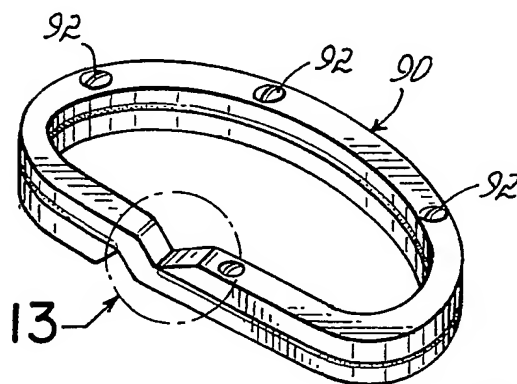


FIG. 12

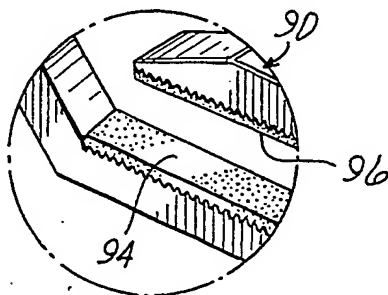
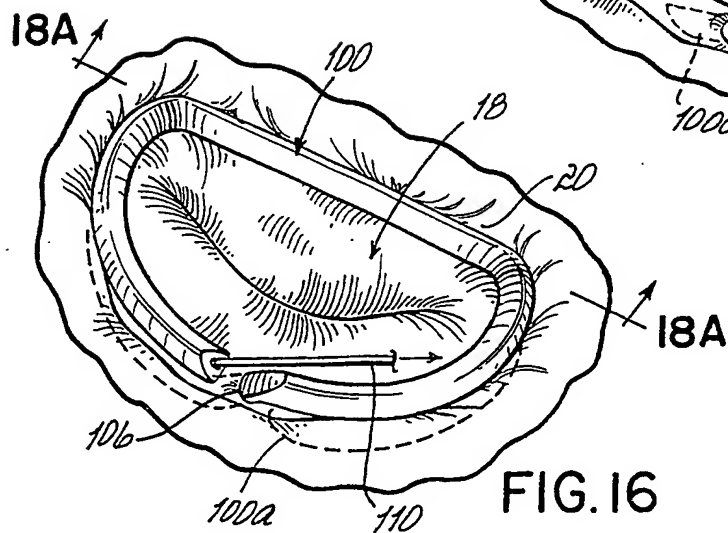
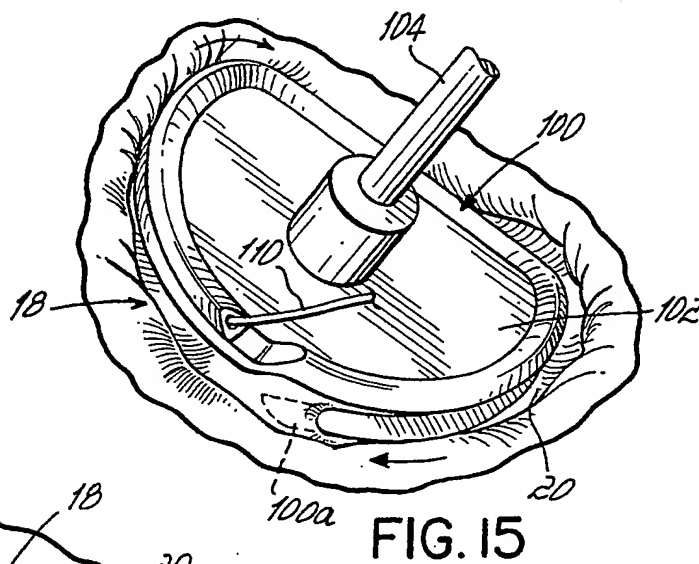
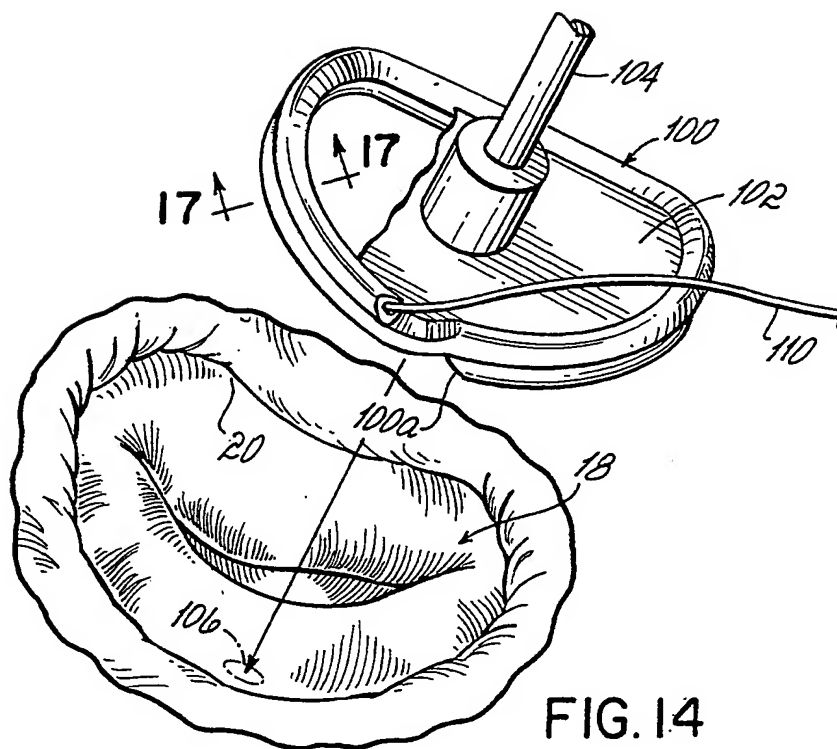


FIG. 13



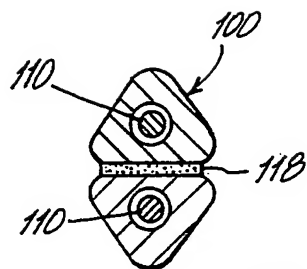


FIG. 17

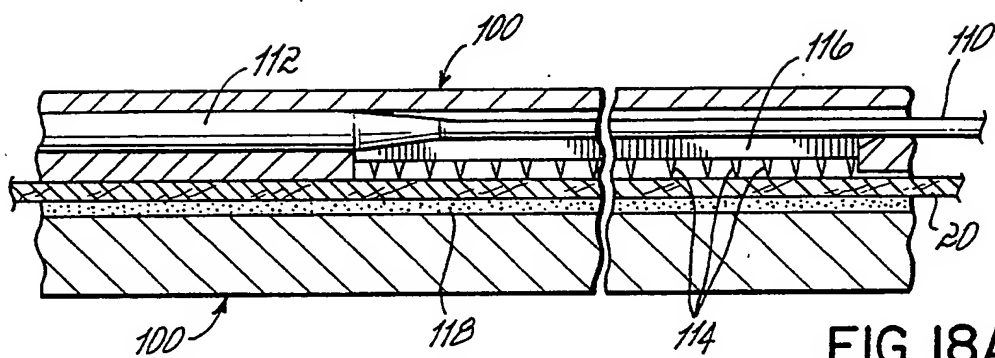


FIG. 18A

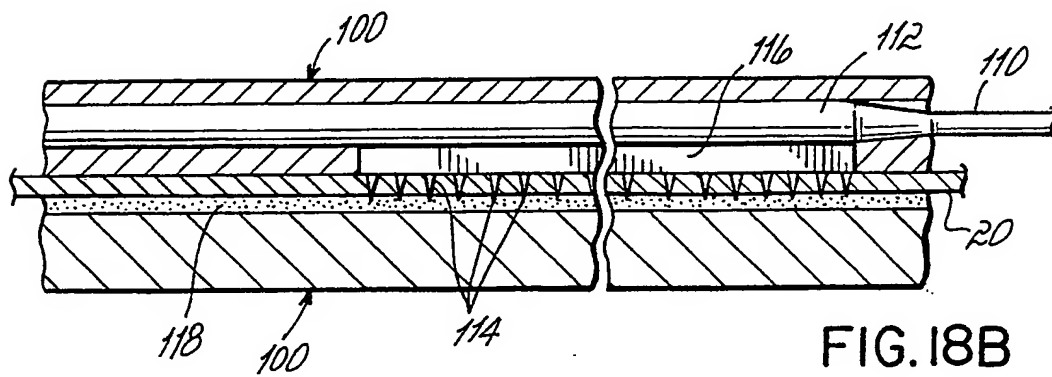


FIG. 18B

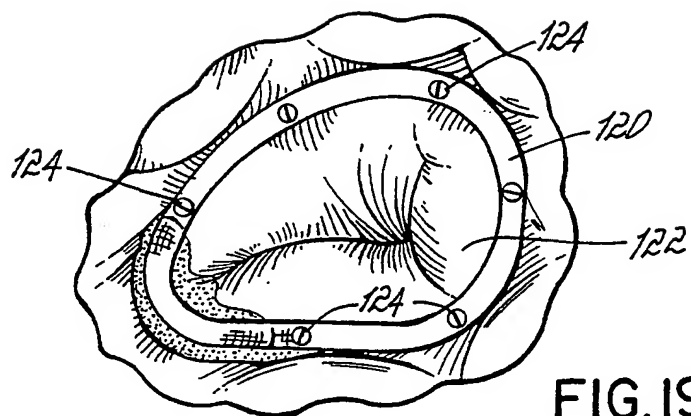


FIG. 19

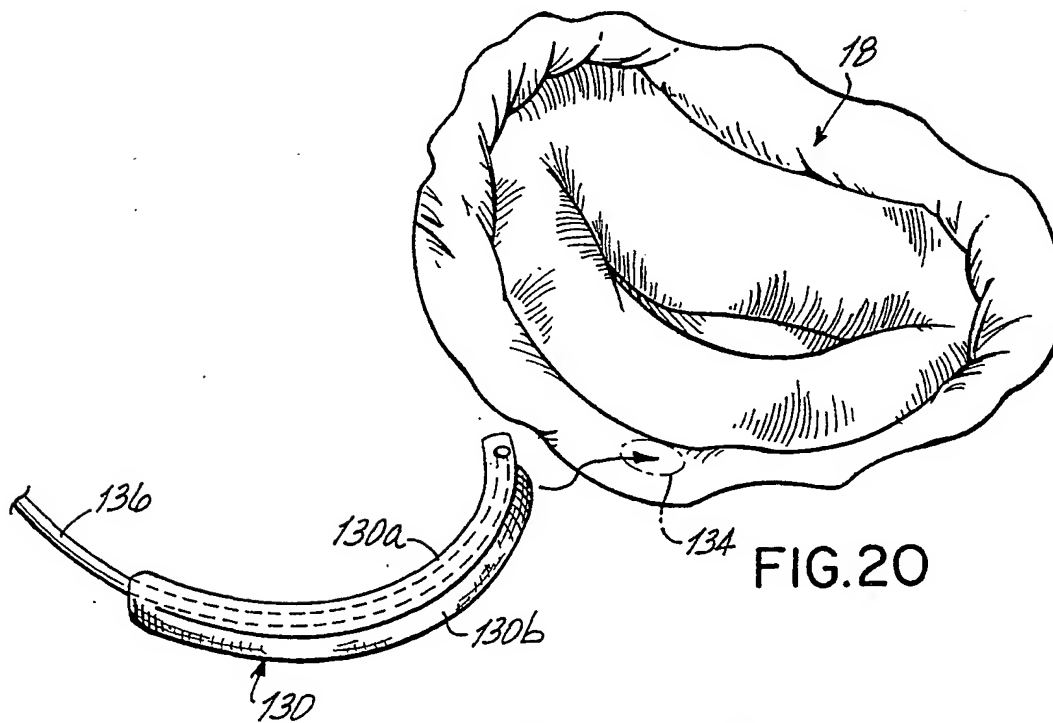


FIG. 20

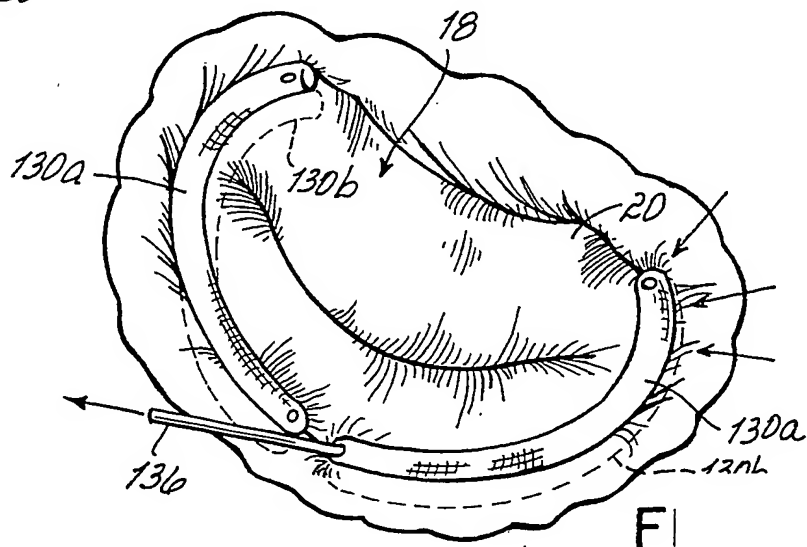
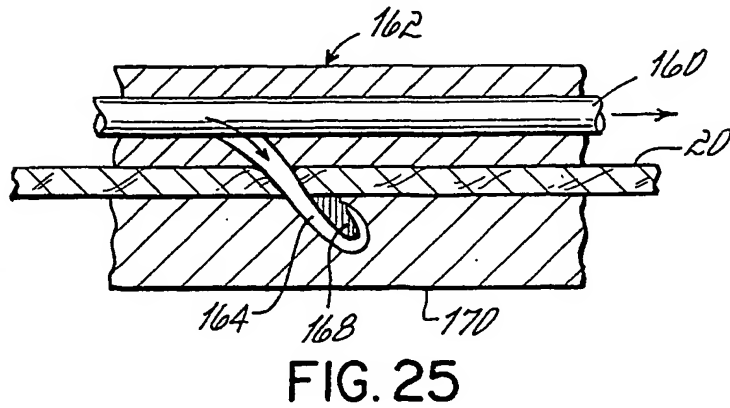
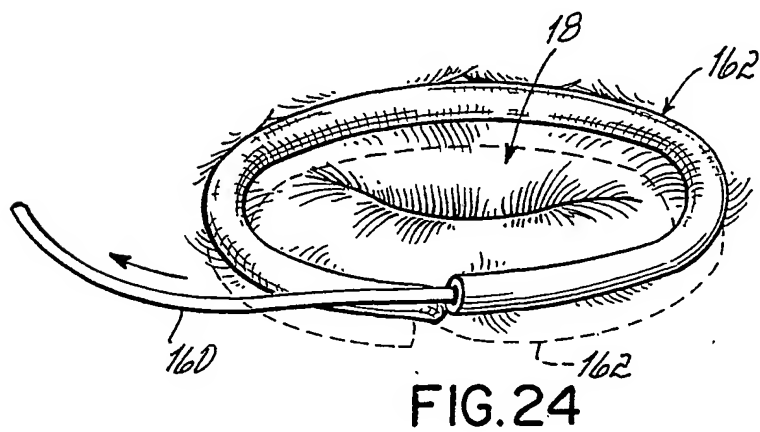
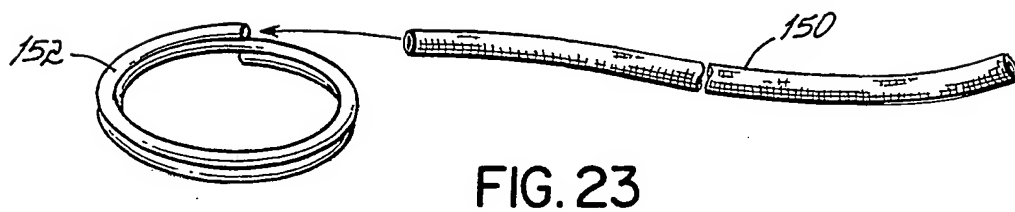
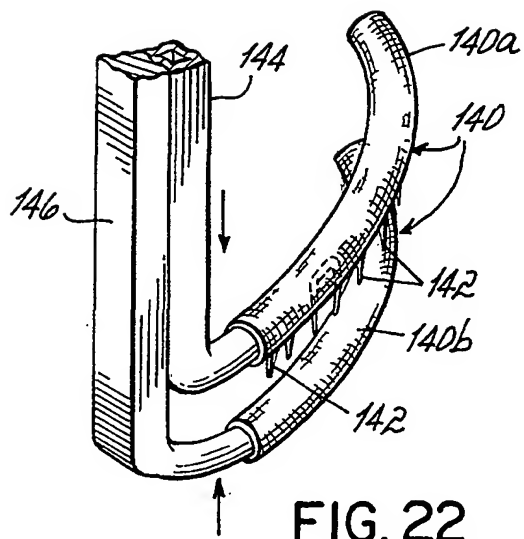
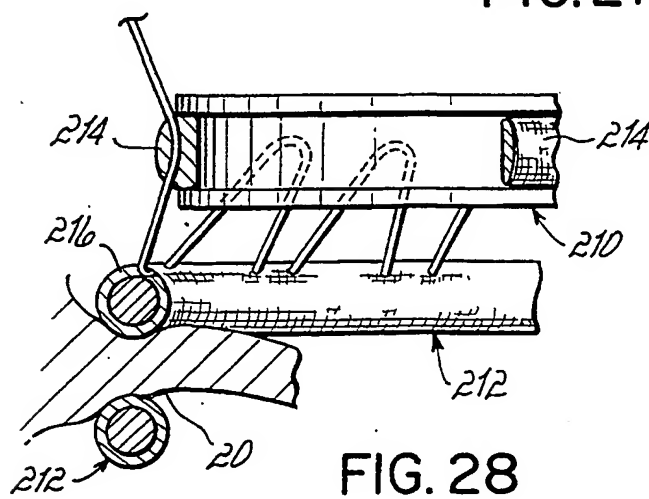
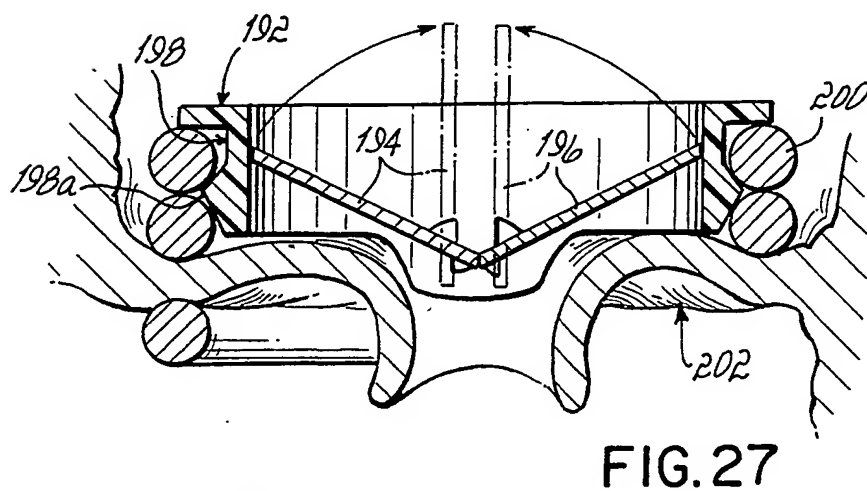
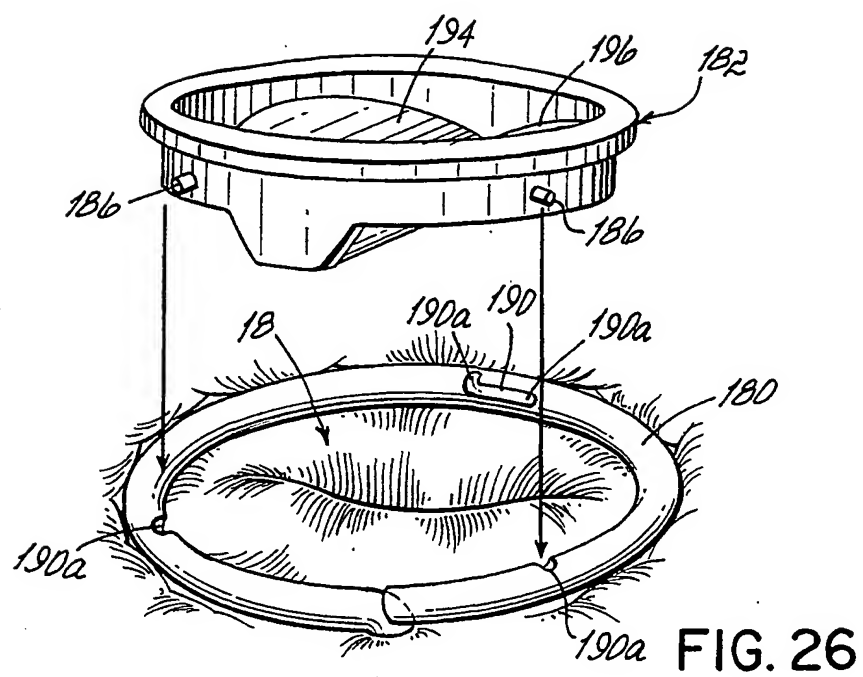


FIG. 21





12/16

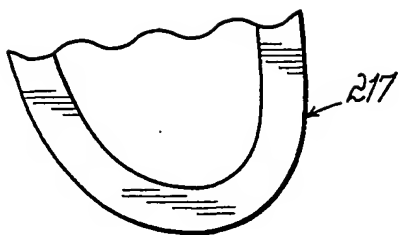


FIG. 29



FIG. 29A

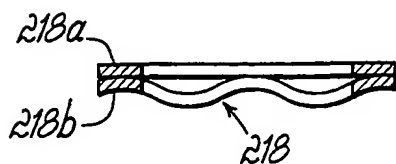


FIG. 29B

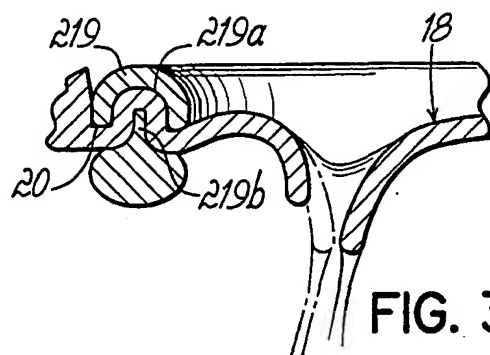


FIG. 30

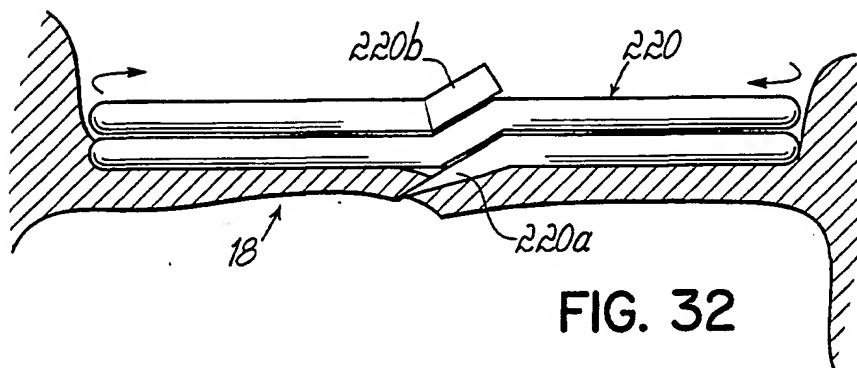


FIG. 32

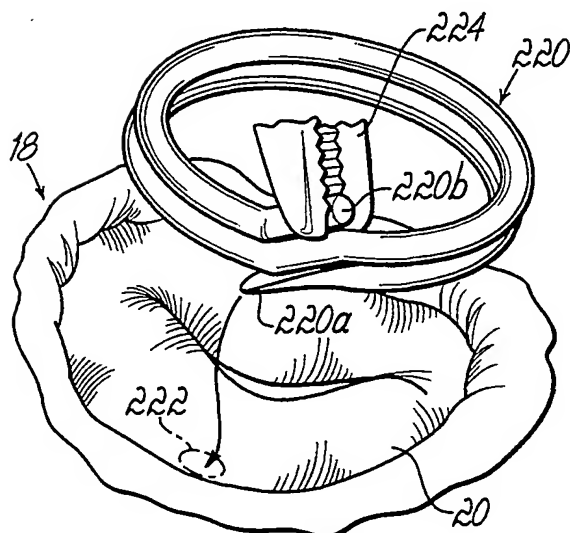


FIG. 31

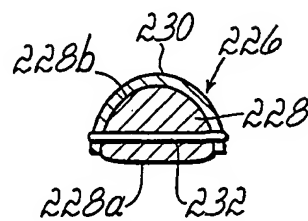


FIG. 33

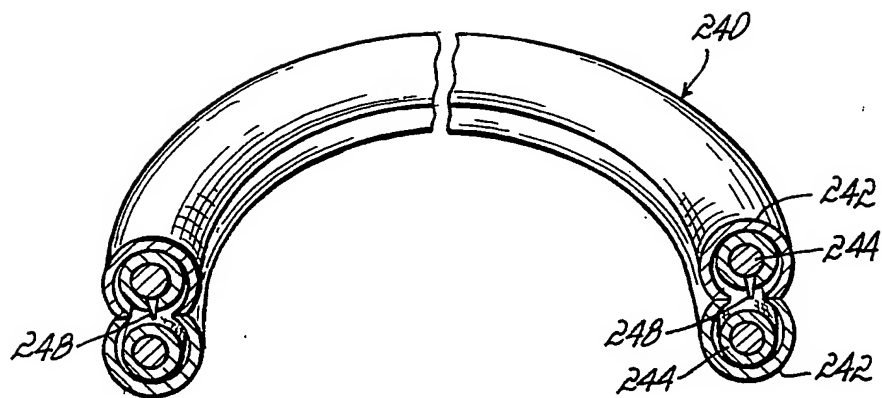


FIG. 34A

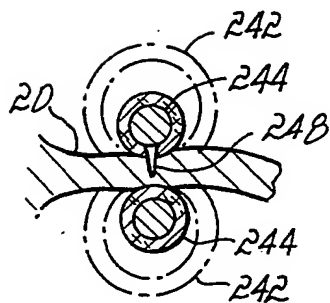


FIG. 34B

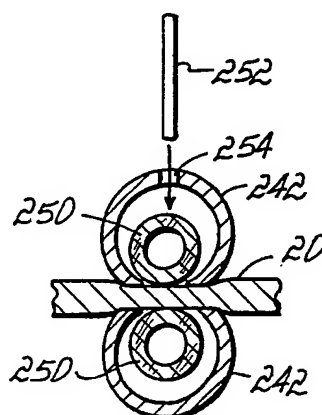


FIG. 35A

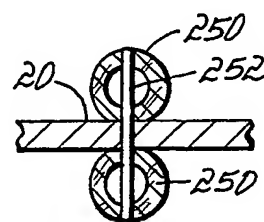


FIG. 35B

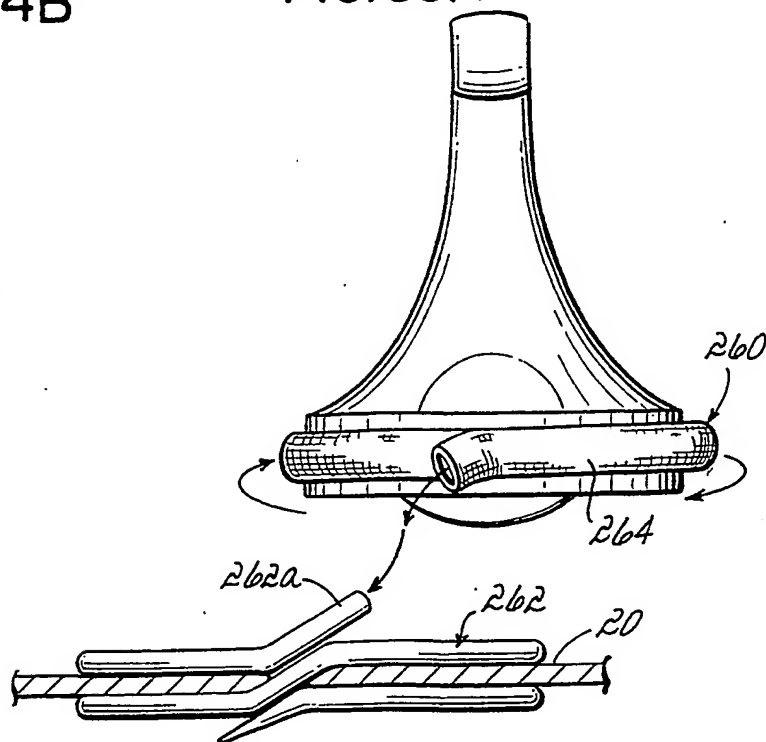
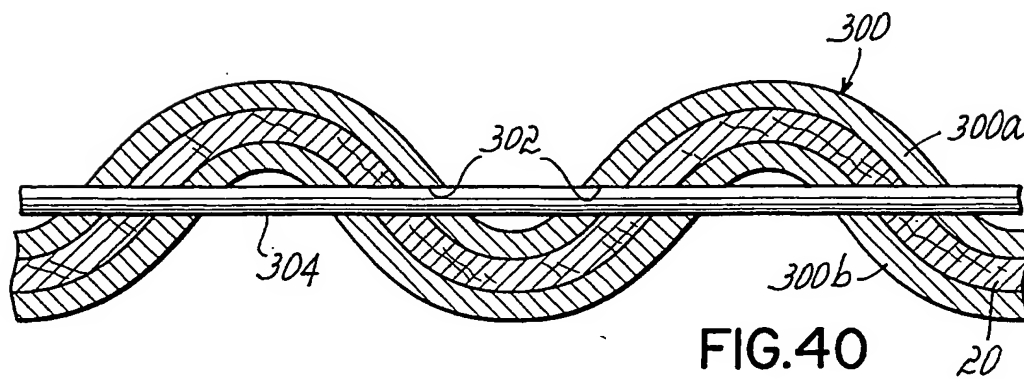
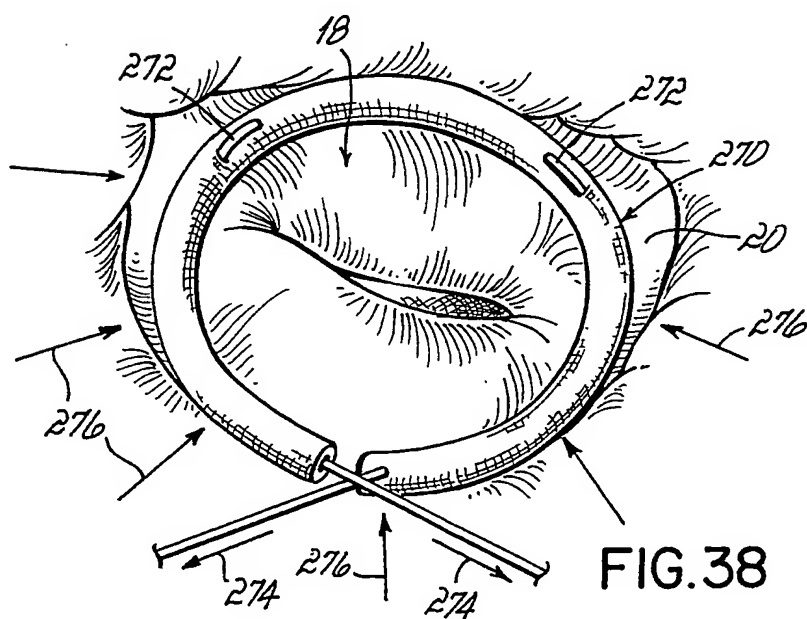
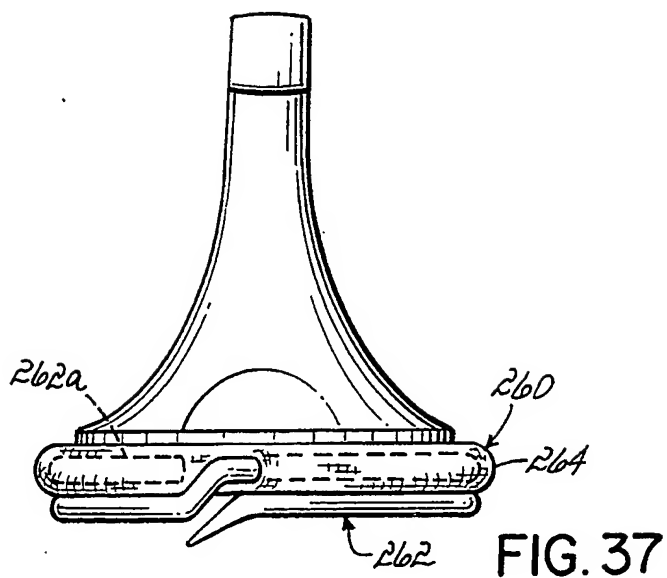


FIG. 36

14/16



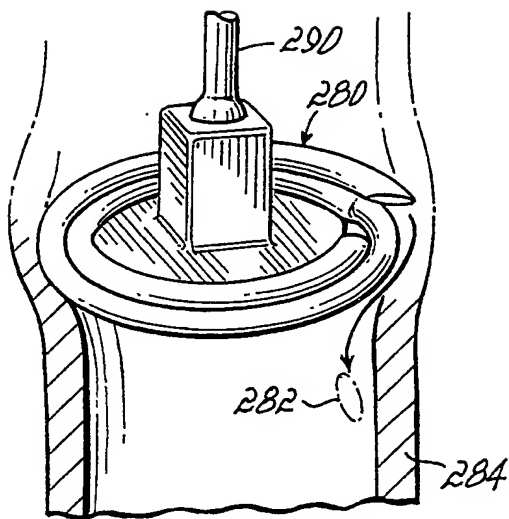


FIG. 39A

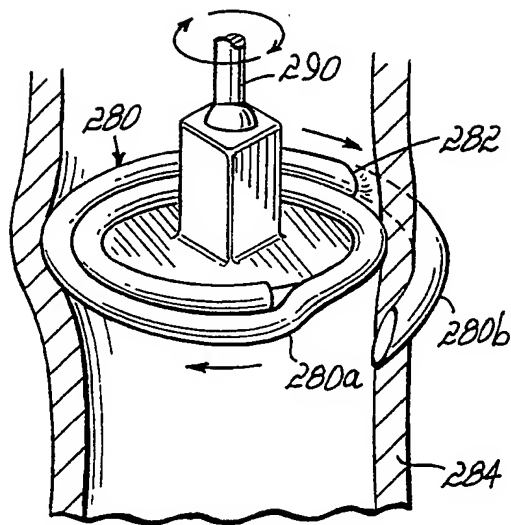


FIG. 39B

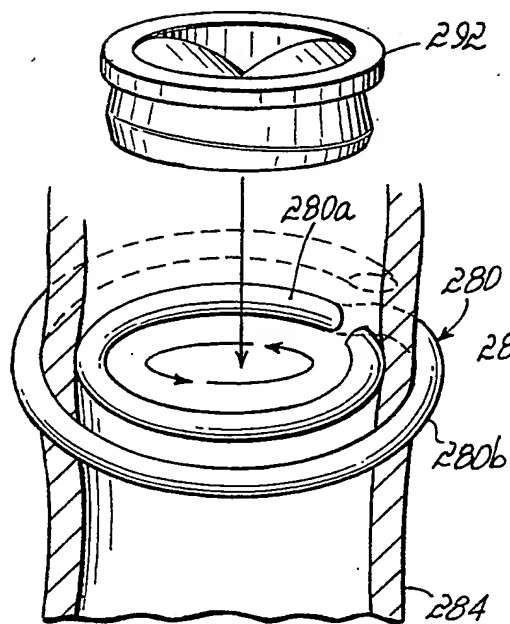


FIG. 39C

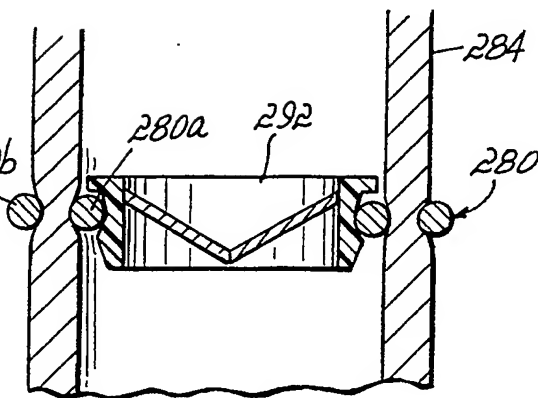


FIG. 39D

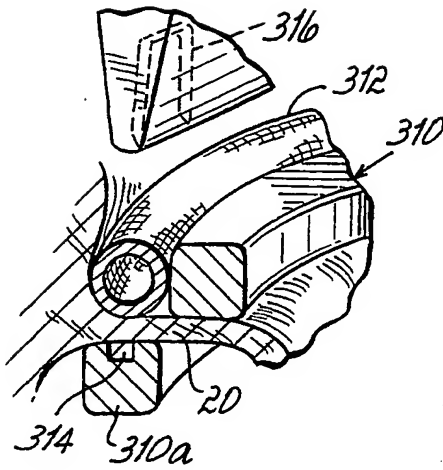


FIG. 41A

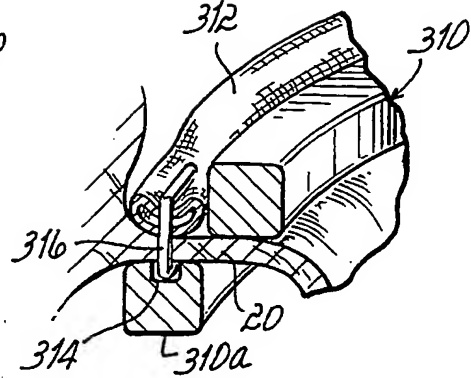


FIG. 41B

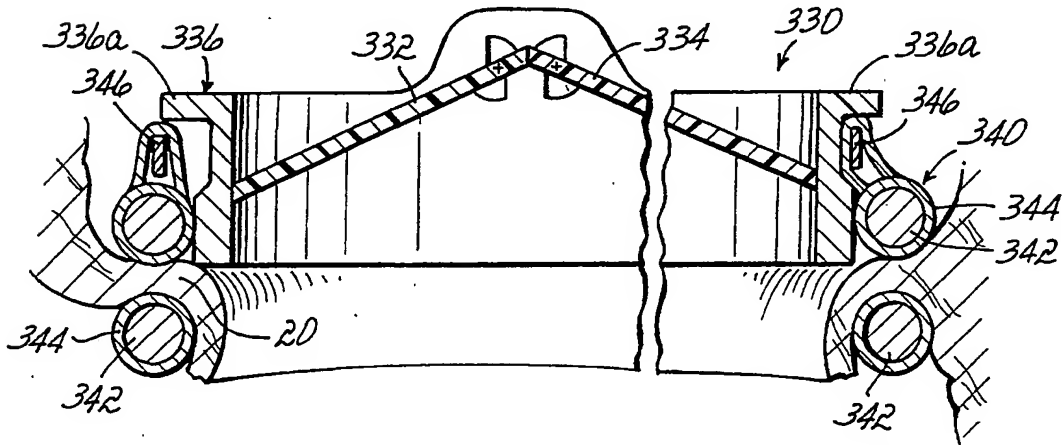


FIG. 42

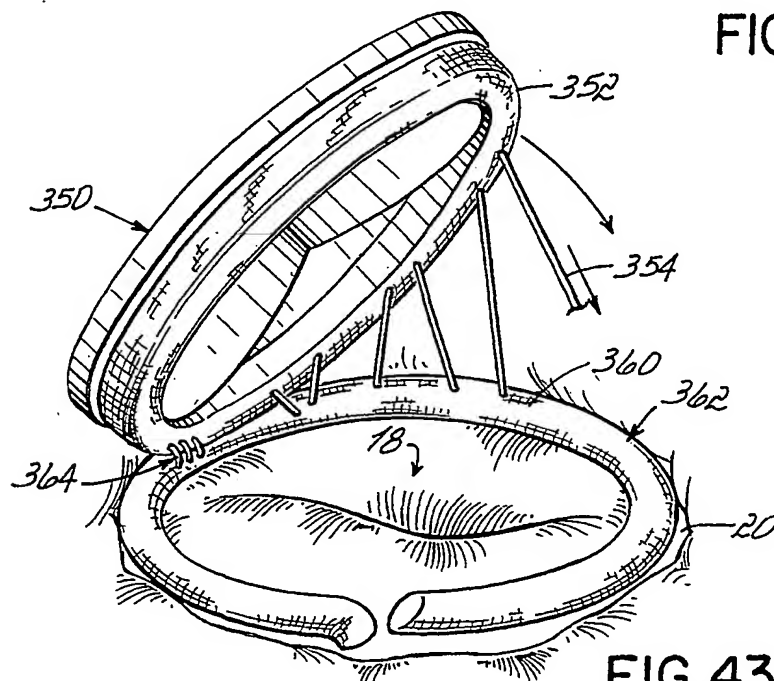


FIG. 43

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/17534

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 602 911 A (AHMADI ALI ET AL) 29 July 1986 (1986-07-29) claims; figures ---	1,13,14, 19,20,31
A	WO 95 16407 A (BRIGHAM & WOMENS HOSPITAL) 22 June 1995 (1995-06-22) abstract; figures ----	1,19,27
A	DE 196 05 042 A (FIGULLA HANS REINER PROF DR ME) 15 January 1998 (1998-01-15) the whole document ---	27,29,34
A	WO 99 04730 A (BAXTER INT) 4 February 1999 (1999-02-04) claims; figures -----	21

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- 'A' document defining the general state of the art which is not considered to be of particular relevance
- 'E' earlier document but published on or after the international filing date
- 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- 'O' document referring to an oral disclosure, use, exhibition or other means
- 'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

'8' document member of the same patent family

Date of the actual completion of the international search

5 December 2001

Date of mailing of the international search report

12/12/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Neumann, E

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-19,20,21-26,31-33

1.1. Claims: 1-19

A device comprising a first and a second support ring which is connected to said first support ring to form a coiled configuration

1.2. Claim : 20

A device comprising a valve support device and a coiled shaped carrier

1.3. Claims: 21-26

A device comprising a catheter and an elongate valve support member which assumes a coiled configuration

1.4. Claims: 31-33

A device comprising a carrier and a coiled shaped member

2. Claims: 27-30

A device comprising a first and second support member formed from shape-memory alloy

3. Claims: 34-42

A replacement valve device comprising a first and second support ring and a replacement valve coupled to aid second support ring

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/17534

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4602911	A	29-07-1986	DE 3406469 A1 DE 3230858 A1	29-08-1985 01-03-1984
WO 9516407	A	22-06-1995	AU 1301095 A WO 9516407 A1 US 5584879 A	03-07-1995 22-06-1995 17-12-1996
DE 19605042	A	15-01-1998	DE 19605042 A1	15-01-1998
WO 9904730	A	04-02-1999	AU 8497498 A EP 0996393 A1 WO 9904730 A1 US 6217610 B1 US 2001021874 A1	16-02-1999 03-05-2000 04-02-1999 17-04-2001 13-09-2001